

## **REMARKS**

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were pending and examined in the Office Action dated November 2, 2006. Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 were rejected in that Office Action. No claims have been added, modified, or deleted by this Response. Applicants respectfully request reconsideration of this application.

## **REJECTIONS UNDER 35 U.S.C. § 103**

### **Combination of the Alt `600 and Zhu `215 Patents**

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 stand rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Alt (5,855,600) in view of Zhu, et al. (6,399,215). In the present seventh non-final Office Action, it appears to Applicants that the Examiner has merely applied the Alt `600 patent and the Zhu `215 patent in the same manner as she did in the Office Action dated 5/10/2006, including the text verbatim from that previous Office Action. Accordingly, Applicants incorporate herein each of the arguments and remarks from Applicants' Response dated August 7, 2006.

Applicants appreciate the Examiner's consideration of Applicants' arguments contained in their Response to the Office Action dated 5/10/2006. The Examiner disagrees with Applicants' arguments; however, she fails to address each of Applicants' arguments, merely repeating her conclusory statement that Applicants' claimed invention would be an obvious modification of Alt `600.

Applicants respectfully submit that the Examiner fails to appreciate that neither the Alt `600 nor Zhu `215 patents enable providing a metal alloy having an average grain size in the range of one to ten microns. The Alt `600 patent does not teach that the disclosed stent is made from a material that has an average grain size of one to ten microns. No starting materials other than commercially pure titanium, which is not an alloy, are disclosed in the Zhu `215 patent. Consequently, the Examiner's statement that

one of ordinary skill in the art would select or make the alloy disclosed by Alt as an ultrafine grain alloy is without merit and cannot stand up to scrutiny under appeal.

Even if there was some teaching or suggestion in the Alt `600 or Zhu `215 patents to combine the references, which there is not, the Examiner has not and cannot demonstrate that there is available to one of ordinary skill in the art a metal alloy substrate having an average grain size in the range of one to ten microns to select for use in a medical device, as claimed by Applicants. Applicants respectfully submit that the Examiner has not carried the burden to establish a *prima facie* case of obviousness by citation to one or more prior art references that teach or suggest each and every claim limitation of Applicants' claims. Thus, Applicants respectfully submit that the rejection of Applicants' claims over Alt `600 in view of Zhu `215 under § 103(a) is improper and must be withdrawn.

#### **Alt `600 Patent Standing Alone**

Claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 stand rejected pursuant to 35 U.S.C. § 103(a) as being unpatentable over Alt (5,855,600). Again, the Examiner acknowledges that the Alt `600 patent does not teach that the disclosed stent is made from a material (substrate) that has an average grain size of one to ten microns. The prior art made of record and not relied upon does not overcome this deficiency of the Alt `600 patent. Applicants respectfully and strongly disagree with the Examiner's erroneous statement that alloys having a grain size as claimed by Applicants were well known in the art. After seven Office Actions, the Examiner has yet to cite any single reference suitable for anticipating or any combination of references suitable for rendering obvious Applicants' claims.

The Examiner has used impermissible hindsight gleaned from Applicants' teachings to conclude that a medical device formed from a metal alloy having an average grain size of one to ten microns is obvious to one having ordinary skill in the art. In the

present Office Action, the Examiner merely refers to two obscure references - Roberts (4,021,271) and Mahoney et al. (4,919,323) - that do not anticipate Applicants' claims and that are unsuitable for combination with the Alt `600 patent. Applicants note that the Examiner did not even attempt to combine the Roberts `271 and Mahoney `323 patents with Alt `600.

It is Applicants' position that the alloys and any methods of making the alloys disclosed in the Roberts `271 and Mahoney `323 patents would not suggest to one having ordinary skill in the art to substitute the alloys of Alt `600 with Applicants' claimed alloys. The Examiner apparently fails to appreciate that the alloys claimed by Applicants (for example, stainless steel, cobalt-chromium and nickel-titanium) formed with an average grain size in the range of one to ten microns were not known materials prior to the time of Applicants' invention. Therefore, the Examiner's statement that Applicants' invention "would amount to mere substitution of one known material for another within the art" is unsupported and erroneous.

Moreover, the Roberts `271 and Mahoney `323 patents alone do not and cannot represent the state of the art of materials used for medical device substrates at the time the present application was filed. The Roberts `271 patent discloses methods for processing aluminum-magnesium alloys that one having ordinary skill in the art would not recognize as teaching how to prepare a fine grain alloy for use as a medical device substrate. The Mahoney `323 patent does not disclose how the special fine grain Inconel 718 alloy was formed. Therefore, neither Roberts `271 nor Mahoney `323 are enabling references for making fine-grained medical device substrates. It is the burden of the Examiner to apply each of the elements of Graham, including identifying the level of ordinary skill in the art, which has not been properly done. Accordingly, Applicants respectfully submit that the failure to do so is fatal to the Examiner's rejection and therefore cannot be sustained upon appeal -- see MPEP §§ 2141, 2141.03.

Applicants also respectfully disagree with the Examiner's assertion that the specific alloys claimed do not solve any stated problem. In fact, Applicants' specification states that the alloys must be suitable for use in intravascular and other medical devices that are implanted or used in the body (page 7, lines 1-18). Furthermore, Alt `600 requires that the only suitable materials for use in the disclosed stent must be "medical grade" (column 5, lines 53-55). The Examiner has not provided evidence that such medical grade fine grained materials were available for a "mere substitution of one known material for another" at the time Applicants' application was filed. For example, the Roberts `271 patent describes aluminum-magnesium alloys that are not disclosed by Roberts `271 or asserted by the Examiner to be suitable for use in a medical device. It is Applicants' position that aluminum-based alloys, such as those disclosed in the Roberts `271 patent, are well known by those having ordinary skill in the art to be unsuitable for use in an implantable medical device. It follows, therefore, that Roberts `271 teaches nothing to one having ordinary skill in the art about modifying the disclosure of the Alt `600 patent.

Similarly, the Mahoney `323 patent describes a "special fine grain" nickel based alloy (Inconel 718), apparently designed for use in aerospace materials, and was not disclosed by Mahoney `323 or asserted by the Examiner to be suitable for use in a medical device. The example of a fine grain nickel alloy disclosed by Mahoney `323 was formed as a sheet to be bonded to stainless steel (column 3, lines 34-46), and was not intended for use as a substrate to form a medical device. It is Applicants' position that the special fine grain Inconel 718 alloy as disclosed by Mahoney `323 would not be recognized by one having ordinary skill in the art to be suitable for use in an implantable medical device. It follows, therefore, that Mahoney `323 teaches nothing to one having ordinary skill in the art about modifying the disclosure of the Alt `600 patent.

Thus, the Examiner's statement that it would have been obvious to one having ordinary skill in the art at the time Applicants' invention was made to substitute the alloys of Alt `600 with the fine grain alloys as claimed by Applicants is without support and

cannot be sustained upon appeal. Accordingly, Applicants respectfully submit that the rejection of Applicants' claims under § 103(a) over Alt '600 standing alone is improper and must be withdrawn.

### CONCLUSION

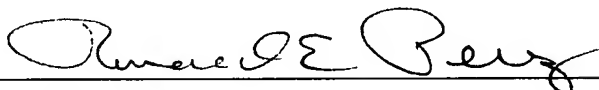
In view of the foregoing, Applicants respectfully submit that all presently pending claims 1, 3-10, 14-16, 22-24, 26-29 and 41-45 are in condition for allowance, and that the application should be passed to issue. The Examiner is encouraged to contact the undersigned should there be any questions or resolvable matters regarding this application.

Respectfully submitted,

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Dated: February 2, 2007

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